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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,504	10/19/2001	Steven J. Siegel	PENN-0789	3358

7590 09/13/2004

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/046,504	SIEGEL ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment and remarks filed 06/10/04. Claims 1-10 are pending.

Specification

1. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

2. Claim 4 remains rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for acetone, does not reasonably provide enablement for all organic solvents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicants argue that Examiner improperly concluded that the disclosure is not enabling based on analysis of only a portion of the factors while one or more of the factors are ignored. Applicants further argue that a skilled artisan would not need unreasonable amount of experimentation to ascertain those solvents that are suitable for dissolving haloperidol and a biodegradable polymer.

3. Applicants' arguments filed 06/10/04 have been fully considered but they are not persuasive.

4. Claim 4 was rejected on the basis that the scope of the claims broadly covers all organic solvents while the disclosure enables only acetone. There are no other organic solvents that are disclosed by applicants to be suitable for the dissolution of haloperidol and the biodegradable polymer. From the disclosure one would be led to use acetone and not other organic solvents such as ethyl acetate, tertrahydrofuran, methanol, benzene, glycols and paraffins, to list a few. The disclosure enables acetone while the claim directs the artisan to use organic solvents. What are the organic solvents that applicants consider as suitable in the invention?

Claim Rejections - 35 USC § 102

5. Claims 1 and 2 remain rejected under 35 U.S.C. 102(b) as being anticipated by Kino et al. (WO 94/10982, cited in applicants' specification, abstract).

Applicants traversed the above rejection in that Kino discloses injectable formulation by citing column 3, lines 49-52; column 4, lines 59-61; and column 5, lines 10-12 of Kino's US 5,656,299.

6. Applicants' arguments filed 06/10/04 have been fully considered but they are not persuasive.

The WO 94/10982 reference in the abstract recognizes that compositions comprising haloperidol and lactic acid/glycolic acid copolymer can be implanted but also recognizes that the need for surgical implantation is avoided and administration is carried out with negligible discomfort with hypodermic and intramuscular injection of said composition. This in itself

does not constitute a negative teaching or a teaching away from the instant claims. Specifically, in Kino, there is recognition that the haloperidol-biodegradable polymer device is implantable.

It is noted that the ability to remove the drug delivery system has no patentable weight in the instant claims.

7. Claims 1-3 remain rejected under 35 U.S.C. 102(b) as being anticipated by Cheng et al. (J. Controlled Release, 1988, 203-212, cited by applicants on form PTO 1449).

Applicants argue that the implantable device of the instant claims are removable and thus offers some level/degree of reversibility not available with the depot formulation of Cheng.

8. Applicants' arguments filed 06/10/04 have been fully considered but they are not persuasive.

Although Cheng in the teaching section cited by applicants discloses that "oral dosage forms (tablets, capsules and solutions) and long acting depot injections are presently available for clinical practice" and "depot formulations have several advantages over oral dosage forms," Cheng does not teach away from haloperidol-biodegradable polymer composition that can be implanted. Specifically, the instant claims are directed to compositions that contain haloperidol and biodegradable polymer where the biodegradable polymer is lactide-co-glycolide (claim 2) and the lactide-co-glycolide is 50% polylactide and 50% polyglycolide (claim 3). Cheng specifically discloses, in column 2, lines 3-7 of page 204, that the PLG 50:50 drug deliver copolymer can be implanted.

It is noted that the ability to remove the drug delivery system has no patentable weight in the instant claims.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Brodbeck et al. (US 6,130,200).

Brodbeck discloses "methods and compositions for systemically or locally administering by implantation a beneficial agent to a subject" (abstract). Haloperidol is one of the beneficial agents in Brodbeck (column 20, line 23). The composition comprises 50:50 poly (lactide-co-glycolide) copolymers and in the preparation solvents are involved (column 5, lines 24-56). Brodbeck discloses treating by implanting a delivery system comprising a beneficial agent (column 4, lines 57-64) and the system is the haloperidol-poly (lactide-co-glycolide) copolymer delivery system described above.

An implant has the option of being removable since a surgically implanted device can also be removed surgically. Since the carrier is biodegradable, the removal would depend on when the removal is initiated before the carrier is completely degraded. Brodbeck meets the limitations of the claims.

Claim Rejections - 35 USC § 103

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Claims 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. (J. Controlled Release, 1988, 203-212, cited by applicants on form PTO 1449).

Cheng discloses a method of preparing delivery device that comprises poly(lactide-co-glycolide) copolymer microspheres, organic solvent such as dichloromethane, polyvinyl alcohol by a process of emulsification-solvent evaporation (section 2). The difference between Cheng and the instant claims is that Cheng does not specifically state that the composition is formulated as an implant. But in lines 3-7 of column 2, page 204, Cheng discloses that the composition can be implanted. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare haloperidol-poly(lactide-co-glycolide) copolymer composition. One having ordinary skill in the art would have been motivated to formulate the composition into an implant with the expectation of improving the degree of compliance and more predictable absorption.

An implant has the option of being removable since a surgically implanted device can also be removed surgically. Since the carrier is biodegradable, the removal would depend on when the removal is initiated before the carrier is completely degraded.

Applicants' argument regarding the obviousness rejection over Cheng et al. (J. Controlled Release, 1988, 203-212, cited by applicants on form PTO 1449) in view of Kino (WO 94/10982, cited in applicants' specification, abstract) appears to be moot because the rejection is redone. However, both Kino and Cheng disclose that haloperidol-poly(lactide-co-glycolide) copolymer composition is implantable.

12. Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brodbeck et al. (US 6,130,200).

Brodbeck discloses implanting composition comprising haloperidol and poly(lactide-co-glycolide) copolymer to treat a subject in need thereof. Brodbeck does not disclose treating

psychotic conditions. However, it is known that haloperidol is an antipsychotic agent (see Kino, WO 94/10982, abstract, as a teaching reference). The method of claim 7 administers and the prior art administers by implantation. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to implant the haloperidol composition in a subject in need of treatment. One having ordinary skill in the art would have been motivated to implant the haloperidol composition with the expectation of treating psychosis.

13. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification and in the claims.

Question:

The drug delivery system has a biodegradable polymer. When is the system removable and removable form what or where?

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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